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10/700,738

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Brian Pope

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |                                    |  |
|------------------------------|--|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/700,738     | <b>Applicant(s)</b><br>POPE ET AL. |  |
|                              | <b>Examiner</b><br>ELIZABETH R. MACNEILL | <b>Art Unit</b><br>3767            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-36 and 46-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-36 and 46-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3,5-31, 46-67,72-74, and 78 are rejected under 35 U.S.C. 103(a) as being anticipated by JHUBOO (US 5,501,665).

Regarding claims 1,13,46,55,74,78 Jhuboo teaches a device and a method of automatically detecting an occlusion in a fluid line of a syringe pump, the syringe pump (8) including a housing (10) adapted to support a syringe (12) containing a plunger (18) moveable inside the syringe by pushing an end of a plunger with a pusher (14) to expel fluid from an outlet of the syringe into a fluid line (tube shown in Figure 2) connected to the outlet and configured to carry the fluid under pressure to a patient, the method comprising: mounting the syringe onto the housing with the plunger end extended; coupling the pusher to the end of the plunger; initiating a pumping sequence to cause the fluid to flow into the fluid line; during the pumping sequence, using a sensor (36) to determine a first force value indicative of force in the fluid line at time T1; during the pumping sequence, determining a second force value indicative of force in the fluid line at time T2; and providing an indication of the occlusion if a relationship between the

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first and second force values departs from an expected slope relationship. Col 1 lines 33-44.

Jhuboo uses the terms “initial pressure” and “second pressure” in the description as mean pressures (Col 4, lines 55-65). Jhuboo does not disclose using “instantaneous force values” in his equations (note that force and pressure are interchangeable since the force is used to calculate the pressure, Col 4 at line 30). Jhuboo suggests using an instantaneous force at Col 5, lines 40-52. One of ordinary skill in the art at the time the invention was made would have expected the method of Jhuboo to perform equally well using an instantaneous force value since Jhuboo discloses that it would react faster to an obstruction. By using the English description of the formulae given in Col 1, the examiner believes one of ordinary skill in the art would understand the use of instantaneous forces.

Regarding claims 2,14,24 an alarm is triggered when an occlusion is detected; therefore a no-alarm condition indicates there is no occlusion

Regarding claims 3,15,57 a steady-state condition is determined (gradient constant)

Regarding claims 16-18, the gradient constant is determined from the startup time period and startup fluid volume, since the gradient constant is a function of the flow rate, or a function of volume and time.

Regarding claims 5,23,48,60 a window (time interval) is determined for T1 and T2

Regarding claims 6,25,56,58,and 61 an expected slope relationship (gradient constant) is compared to the first and second force values

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Regarding claims 7,8,10,26,27,29,50,52,62,63,65 a trial slope (and occlusion slope, or gradient constant) (flow rate) is determined using the first and second force values and compared to an occlusion slope

Regarding claims 9,28,47,49,51, and 64 the expected relationship is compared to the relationship between the first and second force values to determine if an occlusion exists.

Regarding claims 11,21,30,66 a time window is shifted to obtain an additional force value

Regarding claims 12,31,67 the indication of occlusion is cancelled when the comparison between the trial slope and the occlusion slope (or gradient constant) are compared

Regarding claims 19,20,22,59 a sensor (force transducer 36) is used to determine the first and second force values.

Regarding claims 53,54,72, and 73, a third pressure measurement after time T3 is taken to be compared to the first two measurements.

3. Claims 32,34,36,68,70,76,77 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhuboo as applied to claims 13,55,74 and 78 above, and further in view of Tribe.

As disclosed above, Jhuboo teaches an occlusion detector where the slope of two forces over a time interval is compared to a gradient constant to determine if an occlusion exists. Jhuboo does not discuss altering the fluid flow rate beyond the indication to the user that an occlusion exists via an alarm.

Tribe teaches that an automatic syringe pump can be controlled by an occlusion detector to reverse the flow rate and require manual restart of the pump after an occlusion has occurred (P0005-0009).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the occlusion detector of Jhuboo with the automatic fluid delivery rate controls of Tribe in order to make the pump easy to use and to prevent the user from either ignoring or failing to response to the alarm signals.

4. Claims 33,35,69,71,75, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhuboo as applied to claims 13,40,55,74 and 78 above, and further in view of MOBERG (US 6,485,465).

Regarding claims 33,35,45,69,71,75, and 79, Jhuboo teaches an occlusion detector where the slope of two forces over a time interval is compared to a gradient constant to determine if an occlusion exists. Jhuboo does not discuss the delivery of a bolus from the infusion pump, however any syringe pump is capable of bolus delivery.

Moberg teaches an infusion pump (101) and force occlusion detector (134). Moberg teaches that the occlusion detector automatically responds to force greater than the maximum allowable bolus delivery (Col 6 3<sup>rd</sup> paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the occlusion detector of Jhuboo with the bolus occlusion detection of Moberg in order to prevent a false occlusion alarm resulting in the delivery of a prescribed bolus dose.

***Response to Arguments***

5. Applicant's arguments filed 23 January 2008 have been fully considered but they are not persuasive. Regarding the request to make the action nonfinal, the examiner notes that the statutory basis of the rejection was changed after the filing of the RCE to address the new claim limitations and applicant has supplied 12 pages of arguments to address this rejection, which the examiner believes is sufficient to provide applicants a "full and fair examination."

Applicant's arguments regarding using an instantaneous time and force to determine if an occlusion exists are not convincing. Jhuboo teaches that as  $\Delta t$  approaches zero the system is more sensitive and reacts quicker to changes in pressure. He also discloses that prior art devices use instantaneous times/forces to detect occlusions. One of ordinary skill in the art would recognize that Jhuboo's method "being characterized by the fact that it comprises steps consisting of selecting a gradient constant; **measuring an initial pressure** in the perfusion line; **measuring a second pressure** in the perfusion line after a time interval; **subtracting the first pressure from the second pressure** to obtain a first pressure difference; **comparing** the first pressure difference to the gradient constant; and generating a signal if the first pressure difference exceeds or is equal to the gradient constant" (Col 1 at line 35, emphasis added) would apply to instantaneous forces as well as average forces, depending on whether the user wanted a faster, more sensitive detector or a slower, more accurate sensor (Jhuboo Col 5 at line 40).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767